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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
MARMOR II, CHARLES ALAN	
ART UNIT	**PAPER NUMBER**
3736	

DATE MAILED: 04/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/084,763	EPPSTEIN ET AL.	
	Examiner	Art Unit	
	Charles A. Marmor, II	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7,8,32,51,55-60 and 63-83* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *32,51,64,68,69,71-73,78,79 and 81-83* is/are allowed, except for the consideration of the interference issue.

6)☒ Claim(s) *7,8,55-60,63,65-67,70,74-77 and 80* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action is responsive to the Amendment filed October 8, 2004. The Examiner acknowledges the amendments to claims 55-58 and 64, as well as the addition of new claims 65-83. Claims 7, 8, 32, 51, 55-60 and 63-83 are currently pending.

2. The indicated allowability with the exception of the consideration of the interference issue of claims 7, 8 and 63 is withdrawn in view of the newly discovered reference to Schroeder et al. ('985) and the reference to Erickson et al. ('184) when considered in a different light than previously considered. Rejections based on the newly cited references follow.

Claim Objections

3. Claim 69 is objected to because of the following informalities: in line 10, "in" (first occurrence) apparently should be deleted. Appropriate correction is required.

4. Claim 77 is objected to because of the following informalities: in line 6, "that contacts" apparently should read --adapted to contact--. Appropriate correction is required.

5. Claim 81 is objected to because of the following informalities: in line 5, "inblood" apparently should read --in blood--. Appropriate correction is required.

6. Claim 83 is objected to because of the following informalities: in line 7, "or" (first occurrence) apparently should read --of--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 74 and 75 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 74 recites the limitation "the process" in line 9. There is insufficient antecedent basis for this limitation in the claim. There is no "process" recited in the claim prior to this recitation.

Claim 75 recites the limitation "the process" in line 9. There is insufficient antecedent basis for this limitation in the claim. There is no "process" recited in the claim prior to this recitation.

Claim Rejections - 35 USC § 102

9. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

10. Claim 7 is rejected under 35 U.S.C. 102(b) as being anticipated by Schroeder et al. ('985). Schroeder et al. teach an integrated device including a case (7); a pad (5) that is partially disposed within the case (7) that receives and transports a biological sample

containing an analyte; a detector (10, 12) in fluid communication with the pad (5), disposed within the case (7), adapted for detecting the presence and quantifying the concentration of glucose in the sample, and that is in communication with a display (31) for illustrating the results; and a strap (1) for holding the pad (5) to an area of skin surface; where the case (7) includes at least one opening through which the pad (5) extends to allow the biological sample to contact the portion of the pad (5) that is disposed within the case (7).

11. Claims 55-60, 65-67, 76, 77 and 80 are rejected under 35 U.S.C. 102(b) as being anticipated by Ishibashi ('607).

Upon review of the applications in the chain of continuity for the instant application, it has been determined that a vacuum device or a device mechanically inducing a positive pressure are not initially disclosed until at least U.S. Application Serial No. 08/776,863 filed September 5, 1997. In view of the foregoing, the earliest effective priority date for the vacuum device in the instant application is considered to be September 5, 1997.

Ishibashi teaches an apparatus for obtaining biological fluid, including blood and interstitial fluid, for diagnostic testing. The apparatus includes a device (12) for forming an open hole in an area of skin suitable for extracting a sample and a vacuum chamber (11) for introducing a vacuum onto the area of skin so as to stretch the skin and enhance biological fluid flow, including blood and interstitial fluid, from the skin. A stopper ring seal (15) is pressed against the skin for introducing a positive pressure to the area of skin in order assist in fluid flow from the hole. A switch (16) and an external vacuum device

connected at interface (440) are capable of controlling the pressure level and/or timing of the vacuum and of maintaining the vacuum at a desired pressure level. The stopper ring is capable of controlling the pressure level and timing of the vacuum in accordance with the degree of engagement of the stopper ring with the skin.

Claims 55 and 56 of the instant application further recite that the vacuum device is capable of controlling the pressure level and/or timing of the vacuum, and is capable of maintaining the vacuum at a desired pressure level. However, the specification of the instant application does not disclose exactly how the vacuum device of the present invention is capable of controlling the pressure level and timing of the vacuum or of maintaining the vacuum at a desired pressure level; and is only enabling for these limitations in so much as a conventional pump, syringe device, diaphragm or other source of negative pressure (page 46, first full paragraph of the present specification) would be known to be capable of performing such functions. Nonetheless, Applicant's arguments submitted October 8, 2004 appear to rely on these claimed features in an attempt to distinguish the present invention from the prior art of record. The Examiner respectfully requests that Applicant point to the specific disclosure in the instant application, as originally filed, that provides support and enablement for these claimed features should Applicant choose to maintain similar arguments or be subject to a future rejection under 35 U.S.C. 112, first paragraph.

12. Claims 57, 59 and 60 are rejected under 35 U.S.C. 102(e) as being anticipated by Douglas et al. ('983). Douglas et al. teach an apparatus for obtaining a biological fluid for diagnostic testing. The apparatus (10) includes a first device (26) for forming an open

hole in the skin suitable for extracting a sample of biological fluid and a second device (70,72) for introducing a positive pressure to the area of skin to assist in the fluid flow from the opening. The second device is capable of controlling the timing and the amount of pressure on the area of skin by means of triggers (38,50) and motor (88). The apparatus also includes a vacuum device (26) for introducing a vacuum on to the area of skin to enhance fluid flow from the opening. The second device is capable of controlling the timing of the vacuum by turning the vacuum on or off by means of triggers (38,50). The biological fluid is blood or interstitial fluid (col. 6, lines 49-52).

13. Claims 63, 74 and 75 are rejected under 35 U.S.C. 102(e) as being anticipated by Erickson et al. ('184). Erickson et al. teach an apparatus for interstitial fluid collection and constituent measurement. The apparatus (200') includes a first layer (215'); a porating element (214') disposed on the first layer (215') adapted for forming at least one opening in tissue; a sensor (210', see also column 12, lines 4-40) positioned in fluid communication with the at least one opening in the tissue through the porating element and responsive to a biological fluid collected from the tissue to provide an indication of a characteristic of the biological fluid; and a mechanical element (202', 225') with a small opening (218') therein that is capable of receiving the first layer (215') and the sensor (210') such that the porating element is aligned with the small opening and responsive to downward force thereon such that the surface of the tissue will be caused to bulge into the opening. Erickson et al. further teach a method of harvesting biological fluid from tissue and analyzing the fluid where the layer (206) is placed in contact with the skin; at least one open hole is formed in the skin which held open by porating element (214);

biological fluid is collected from the tissue through an opening in the layer (206); a sensor (210) that is in fluid communication with the opening in the layer at least through the porating element is wetted with biological fluid to measure a characteristic of the biological fluid, where a positive pressure is applied to the layer or an negative pressure is applied to the skin in order to induce flow of biological fluid through the opening (see at least column 7, lines 31-39).

14. Claim 70 is rejected under 35 U.S.C. 102(e) as being anticipated by Terminiello et al. ('979). Terminiello et al. teach an integrated fluid harvesting and analysis device including a first layer (53) positioned in contact with tissue and through which poration is achieved to form an open hole in the tissue and a sensor (64) positioned in fluid communication with the opening in the first layer that is responsive to the collected biological fluid to provide an indication of a characteristic of the biological fluid.

Claim Rejections - 35 USC § 103

15. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

16. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schroeder et al. ('985) in view of Carter et al. ('890). Schroeder et al., as applied to claim 7 hereinabove, teach all of the limitations of the claim except that a surfactant is provided to transport the biological sample across the pad. Carter et al. teach that it was known in the art at the time Applicant's invention was made to use a surfactant with a wicking pad

in order to facilitate transport of a sample across a mesh pad (column 5, lines 13-27). It would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to add a surfactant similar to that of Carter et al. to the wicking pad in a device similar to that of Schroeder et al. in order to facilitate transport of a sample across the pad.

Allowable Subject Matter

17. Claims 32, 51, 64, 68, 69, 71-73, 78, 79 and 81-83 are allowable over the prior art of record except for the consideration of the interference issue.

Response to Arguments

18. Applicant's arguments with respect to the rejection of claims 55, 56 as being anticipated by Dombrowski et al. have been considered but are moot in view of the new ground(s) of rejection. Applicant contends that Dombrowski et al. fail to teach or suggest a device for forming an open hole in skin, a vacuum system for application to the skin surrounding the open hole, maintaining the vacuum pressure at a desired pressure level with the vacuum system, and the use of vacuum to cause the skin to stretch or bulge.

With respect to Applicant's argument that Dombrowski et al. fail to teach or suggest forming an open hole in the skin, this argument is not persuasive. Applicant contends that an "open hole" requires that when the hole is created, it remains open and unobstructed by tissue which would otherwise collapse around it. Applicant further asserts that the "open hole" is formed by removing tissue in an area of skin around the puncture, such as through poration or ablation, or by stretching the skin around the

puncture. This argument is not persuasive, in that Applicant is inappropriately relying on a special definition for the term "open hole" which is not explicitly provided in the disclosure of the instant application as originally filed. The disclosure of the present application fails to set forth what specifically constitutes an "open hole" and any specific time frame for how long the hole must remain open. Broadly interpreted, any puncture in tissue is at least initially an open hole. For example, the puncture hole will be open when the piercing member is disposed in the tissue or when a rim of the piercing aperture applies any pressure to the skin surface. A puncture hole may be considered to remain open for as long as the skin surface remains compromised, even well after the piercing element has been removed and the tissue surrounding the hole collapses upon itself irregardless of whether the hole closes to some degree. Depending on the size or gauge of the piercing element employed, the hole formed thereby may not entirely close for an extended period of time after the piercing element is withdrawn. As long as the tissue has an opening formed therein, the hole may be considered opening. Furthermore, an "open wound" is defined by *The American Heritage® Stedman's Medical Dictionary, Copyright © 2002,* as a "wound in which the injured tissues are exposed to the air." Similarly, an "open hole" in tissue may be considered to be an opening in tissue where the tissue in the vicinity of the hole is exposed to the air, rather than an opening "unobstructed by tissue" as Applicant alleges the terminology "open hole" to mean. In view of the foregoing, the argument that Dombrowski et al., or any other prior art of record, fails to teach or suggest forming an open hole in the skin in not persuasive.

The remainder of Applicant's arguments against the teachings of Dombrowski et al. are moot in view of the rejections citing Ishibashi ('607) set forth hereinabove.

19. Applicant's arguments with respect to the rejection of claims 57, 59 and 60 as anticipated by Douglas et al. have been fully considered but they are not persuasive. Applicant contends that Douglas et al. do not teach creating an open hole by removing tissues or applying stretching forces to the skin by applying a vacuum.

Applicant's argument that Douglas et al. do no teach creating an open hole by removing tissues is not persuasive at least for the same reasons discussed hereinabove with respect the Applicant's arguments against Dombrowski et al. Moreover, the claim language of claim 57 does not require that the open hole be formed by removing tissue, as alleged by Applicant. The claim language merely requires that the hole be formed such that it is suitable for extracting a sample of biological fluid. The apparatus of Douglas et al. meets the requirements of this limitation as claimed.

Applicant's argument that Douglas et al. do no teach applying stretching forces to the skin is not persuasive. It appears that Applicant is inappropriately implying that the skin stretching forces are applied by using a vacuum. Claim 58 of the present application recites such a feature, and the rejection claim 58 citing Douglas et al. has been withdrawn. Claims 57, 59 and 60 require that a positive pressure be applied to the skin in order to assist in the flow of fluid from the opening. Douglas et al. teach several embodiments of stimulator members that meet this requirement of the claims. In view of the foregoing, the rejection of claims 57, 59 and 60 as anticipated by Douglas et al. have been maintained.

20. Applicant's arguments with respect to the rejection of claims as being anticipated by Garcia et al. have been considered but are moot in view of the new ground(s) of rejection. Applicant contends that Garcia et al. fail to teach or suggest a system which uses a vacuum to stretch the skin, controls the pressure to maintain the vacuum at a desired level, or applies a vacuum to the skin adjacent to the incision site. These arguments are moot in view of the new grounds of rejection citing at least one of Ishibashi ('607), Erickson et al. ('184), Schroeder et al. ('985) and Terminiello et al. ('979), as set forth hereinabove.

Conclusion

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles A. Marmor, II whose telephone number is (571) 272-4730. The examiner can normally be reached on M-TH (7:00-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Charles A. Marmor, II
Primary Examiner
Art Unit 3736

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March 28, 2005